Remarks

This Amendment is responsive to the Office Action mailed April 19, 2001 (Paper No. 16), which Office Action was made final. Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Final Rejection, Premature

Applicants respectfully submit that the finality of the Office Action (Paper No. 16) should be withdrawn. Specifically, Applicants note that the application contains material which was presented in the earlier application but was denied entry because "new issues were raised that required further consideration and/or search". (See Paper No. 14). Accordingly, under MPEP § 706.07(b) the finality of the subject rejections is premature. Reconsideration and withdrawal of finality of the Office Action (Paper No. 16) are respectfully requested.

Claims

Claims 25-33, 37-42 and 44-47 were pending. Claims 25-33, 37-42 and 44-47 stand rejected.

Claims 25, 30, 37, 39 and 44 have been amended to more particularly and distinctly define the invention. No new matter is added.

It is believed that entry of this Amendment will not require payment of any additional claim fees. Notwithstanding, Applicants hereby authorize the Commissioner to charge any additional claim fees required by entry of this Amendment to Deposit Account No. 50-0258.

Support

Support for the amendments to the claims is apparent. No new matter is added.

Claim Rejections under 35 U.S.C. § 101

Claims 25-33, 37-42 and 44-47 stand rejected under 35 U.S.C. § 101 as lacking patentable utility. Specifically, the Examiner asserts that

> [t]he claims are drawn to an isolated polynucleotide comprising a first polynucleotide or the full complement of the entire length of the first polynucleotide sequence wherein the first polynucleotide

sequence is at least 95% identical to SEQ ID NO:1 (Claims 25-32 & 34-38), methods for producing the polynucleotide (Claim 33) an isolated polynucleotide encoding a polypeptide of SEQ ID NO:2 (Claims 39-41 & 44-46) and methods for producing the polypeptide (Claims 42 & 47). However, the specification fails to teach a specific utility for the claimed polynucleotide because the function of the polynucleotide or the encoded peptide is not known. The specification teaches the claimed polynucleotide sequences were identified in a DNA library derived from *Streptococcus pneumoniae* 0100993 (page 10, lines 19-20). However, the specification teaches that the polynucleotides may be obtained from other organisms (page 11, lines 27-30) and therefore, the polynucleotides are not *Streptococcus pneumoniae*-specific. The specification suggests that the peptides encoded by the claimed sequences have functions similar to the proteins of the malonyl-CoA:ACP family because polynucleotides encode a peptide having structural similarities to proteins of the malonyl-CoA:ACP family (page 10, lines 27-29). However, the specification does not teach a function for the peptides encoded by the claimed sequences wherein the teaching of a function would include a demonstration of the function (e.g. assays or experimental results). Neither the specification nor the prior art teach a specific utility for the claimed invention. Hence, the claimed polynucleotide and amino acid sequences lack a specific utility. Add therefore, the claimed methods are not supported by a substantial utility. The specification fails to assert any substantial utility for the polynucleotide and amino acid sequences and methods and neither the specification as filed nor any art of record discloses or suggest any utility such that a substantial utility would be established for the sequences and methods. The teaching of a substantial utility would include a real-world use e.g. a polynucleotide or amino acid sequence having a known function wherein expression inhibits or promotes a disease and wherein the method to detect the sequence is diagnostic for the disease. Additionally, the substantial teaching would include a demonstration of the real world use e.g. experimental results. The specification teaches that the claimed sequences may be used in diagnostic assays wherein detection of the sequences will provide a diagnostic method for diagnosis of a disease (page 16, lines 12-14), for the presence of an infection (page 17, lines 20-22) and for the stage of infection and type of infection (page 14, lines 4-6). However, the sequences are not *Streptococcus pneumoniae*-specific (page 11, lines 27-30) and therefore, the specification does not teach a disease or infection for which the sequences may be diagnostic and the specification does not teach experimental results

> demonstrating the diagnosis. The specification teaches the sequences may be used to produce antibodies (page 17, lines 27-31) and the specification teaches the antibodies may be used to identify the polypeptides encoded by the sequences (page 18, lines 19-20). However, the specification does not teach a substantial utility for the anti-polypeptide antibodies (e.g. diagnostics) beyond the obvious detection of the polypeptide itself. The specification teaches the claimed sequences may have utility in the discovery of antibacterial compounds for treatment or inhibition of diseases (page 21, lines 9-10 and 26-27). However, the specification does not teach any antibacterial compounds discovered by using the claimed sequences. The specification teaches the claimed sequences may be used as an antigen for inducing an immunological response (page 22, lines 8-23) and for vaccine production (page 23, lines 22-27). However, the specification does not teach experimental results which demonstrate that the antigens produce an immunological response or have utility as vaccines. The specification does not teach any specific utility nor does the specification teach any substantial utility. Therefore the suggested uses for the claimed sequences are merely means to study the properties of itself. Hence, the specification fails to support a substantial utility for the claimed methods. Because the claimed methods are not supported by a specific utility for the claimed methods. Because the claimed methods are not supported by a specific or substantial utility that is either well known in the art or supported by the specification, the claimed methods are not supported by a well-established utility. The specification and the prior art fail to support a specific and substantial or well established utility for the claimed methods.
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> Applicant argues that the claimed polynucleotides and polypeptides have utility as disgnostic reagents for use in the detection of *Streptococcus pneumonia*. Applicants further argue that the claimed polynucleotides could be used to identify bacterial contamination wherein the bacteriological tests are indicative and not dispositive. These argument are not found persuasive because the recited uses are of a general utility and not specific and substantial or well established and because the specification teaches the claimed polynucleotides may be obtained from other organisms (page 11, lines 27-30). Therefore the claimed polynucleotides do not have a specific and substantial asserted utility or well established utility for the detection of *Streptococcus pneumoniae*.

Applicants maintain their traversal to this rejection on the bases asserted in their response to Paper No. 9. Moreover, Applicants respectfully note that in the event that *Staphylococcus aureus* is

present, the diagnostic reagents of the present invention will detect it. Applicants respectfully submit that the disclosed utility of the claimed polynucleotides and polypeptides as diagnostic reagents for the detection of *Streptococcus pneumoniae* is a specific and substantial utility which is credible. The claimed polynucleotides will identify bacterial contamination when present in, for example, human tissue. Moreover, the scope of the diagnostic specificity is readily determined with quintessentially ordinary experimentation. The Examiner should note that bacteriological tests are traditionally indicative, not dispositive of the identity of a given microbe. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 25-33, 37-42 and 44-47 stand rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner asserts that

> since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants note that at its foundation this rejection asserts lack of utility. As such, an adequate rebuttal under the case law or guidelines for rejections for want of utility under 35 U.S.C. § 101 is an adequate rebuttal even if the rejection is framed under 35 U.S.C. § 112. *See*, the last paragraph of the Revised Utility Examination Guidelines, Federal Register, Volume 64, Number 244, December 21, 1999 ("Utility Guidelines"). For the reasons stated above regarding the rejection under 35 U.S.C. § 101, this rejection is also improper and should be withdrawn. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 25-33, 37-42 and 44-47 stand rejected under 35 U.S.C. § 112, first paragraph, for written description. Specifically, the Examiner asserts that

> [c]laims 25-34 & 37-38 are drawn to an isolated polynucleotide comprising a first polynucleotide or the full complement of the entire length of the first polynucleotide sequence wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO:1 and a process for producing the polypeptide encoded by SEQ ID NO:1. Claims 39-47 are drawn to an isolated polynucleotide comprising a first polynucleotide or the full complement of the entire length of the first polynucleotide sequence wherein the first polynucleotide sequence encodes a polypeptide comprising of SEQ

ID NO:2 and a process for producing the polypeptide. The specification teaches the polynucleotide sequences of SEQ ID NO:1, 3 and 5 and the amino acid sequences of SEQ ID NO:2, 4 and 6. However, the claimed polynucleotide sequences are broadly defined in the specification (page 28, line 12-page 29, line 3) and encompass a large genus of sequences, including genes, gene fragments, DNAs, cDNAs, RNAs, mRNAs, probes and primers each encompassing a large genus of possible sequence having various components, various lengths, various regions and degrees of complementation and various codon usage for amino acid encoding. The claims are broadly drawn to a polynucleotide sequence which is at least 95% identical to SEQ ID NO:1. The claimed sequences 95% identical to SEQ ID NO: 1 encompasses a very large genus of sequences but the specification does not teach which nucleotide sequences are encompassed or excluded by the 95% or how to determine which sequences are encompassed e.g. an algorithm which determines identity. The specification does not teach a representative number of species of the genus encompassed by the claims. The specification teaches that the invention relates to isolated polynucleotides, including the full length gene, that encodes the FabD polypeptide (page 9, lines 29-30) and the specification teaches that polynucleotides broadly encompass any modified or unmodified single, double and triple stranded DNA and/or RNA (page 28, line 12-page 29, line 2). However, the specification does not teach a gene, teaching of which would minimally include the open reading frame, introns, exons, and regulatory regions. The specification does not teach a representative number of the claimed probes and primers, a teaching of which would minimally include the regions of SEQ ID NO:1 to which they bind. The specification teaches SEQ ID NO:1, 2, 3, 4, 5 & 6 but the specification does not teach a representative number of the claimed sequences in sufficient detail that one skilled in the art would reasonably conclude that inventor had possession of the claimed invention at the time the application was filed. The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude the inventor had possession of the claimed invention see *In re Vas-Cath*, Inc. 935 F2d. 1555, 1563, 19 USPQ2d 1111, 1116.

Applicant argues that because the claimed nucleic acids would typically be replicated in vectors comprising the necessary regulatory elements which are not described in the specification and therefore the subject matter not taught in the specification falls within what is conventional and well-known in the art. This argument is not found persuasive because the claims are written so

broadly as to encompass a very large genus of sequences. The recitation "an isolated polynucleotide comprising a first polynucleotide sequence.....wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO:1" encompasses a large genus of polynucleotides including genes and the specification does not teach the claimed genes or a representative number of the claimed species.

Applicant further argues Examples 8 and 11 set forth in the Written Description Guidelines teach examples of allowable claims having equivalent scope to the instant claims. This argument is not found persuasive because Examples 8 and 11 and the instant claims are different in scope. Specifically, in Example 8 the claim is drawn to an isolated nucleic acid sequence, SEQ ID NO:2 and the specification teaches that SEQ ID NO:2 consists of the complete ORF. The scope of Example 8 is limited to nucleic acid sequences comprising SEQ ID NO:2 which is taught in the specification while the scope of the instant claims comprises a large genus of sequences not taught in the specification while the scope of the instant claims comprises a large genus of sequences not taught in the specification. Claim 1 of Example 11 is drawn to an isolated cDNA that encodes protein X (sSEQ ID NO:) and the specification teaches one species of the claimed cDNA however, the Guidelines teach that one of skill could apply the genetic code to envision the claimed genus. The Guidelines teach that an adequate written description of Claim 1 is provided in the specification but Claims 2 and 3 being drawn to allelic variants of SEQ ID NO:2 lack an adequate description. The scope of Example 11, Claim 1 is limited to a cDNA that encodes SEQ ID NO:2 which is taught in the specification while the scope of the instant claims being drawn to a large genus of sequences is much broader than either Example 8 or 11.

Applicants respectfully traverse. One assertion which permeates this rejection is that one skilled in the art allegedly could not comprehend what sequences are encompassed by "95% identity" without the concurrent description of a specific algorithm for determination of % identity. Applicants note that those skilled in the art routinely refer to "% identity" without reciting a specific algorithm for its determination. Also, Applicants note that those skilled in the art readily comprehend what is meant by 95% identity. Another assertion presented in this rejection is that the specification includes an allegedly does not teach a sufficient number of the claimed species. Applicants respectfully note that given the degree of identity to SEQ ID NO:1 recited in the specification and claims and SEQ ID NO:1, one skilled in the art could readily envision the

members of the claimed genus. The specific "[m]ention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute." *In re Robins*, 429 F.2d 452, 456, 166 USPQ 552 (CCPA 1970). Applicants refer the Examiner to Example 11 of the *Revised Interim Written Description Guidelines Training Materials* as an example of a instance where the recitation of a single sequence coupled with a defined relationship to the other members of the claimed genus is sufficient to describe a broad genus. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 25-33, 37-42 and 44-47 stand rejected under 35 U.S.C. § 112, first paragraph, for new matter. Specifically, the Examiner asserts that

> [t]he amendments to the claims recite "wherein the first polynucleotide sequence is not genomic DNA". The amendments are not part of the specification as originally filed and therefore are considered new matter. The originally filed specification recites the claimed molecules include mRNAs, cDNAs, genomic DNAs (page 3, lines 26-28) and therefore the new limitation "not genomic DNA" is considered new matter (see MPEP, 2163.01 and 37 C.F.R. 1.118). An amendment reciting "wherein the first polynucleotide sequence is mRNA or cDNA" would not be considered new matter.

Without conceding the validity of this rejection, Applicants have elected to amend the claims to obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

FEE DEFICIENCY

☒ If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 50-0258.

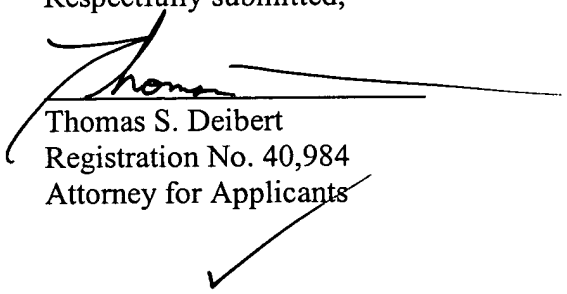
and/or

☒ If any additional fee is required for consideration of this paper, please charge Account No. 50-0258.

Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,



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Detail of claim amendments

25. (Thrice Amended) An isolated polynucleotide comprising a first polynucleotide sequence or the full complement of the entire length of the first polynucleotide sequence, wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO:1 ; and wherein the first polynucleotide sequence detects *Streptococcus pneumoniae* [and wherein the first polynucleotide sequence is not genomic DNA].

30. (Twice Amended) An isolated polynucleotide comprising a first polynucleotide sequence or the full complement of the entire length of the first polynucleotide sequence, wherein the first polynucleotide sequence comprises SEQ ID NO:1 [and wherein the first polynucleotide sequence is not genomic DNA].

37. (Thrice Amended) An isolated polynucleotide comprising a first polynucleotide sequence or the full complement of the entire length of the first polynucleotide sequence, wherein the first polynucleotide sequence hybridizes to the full complement of SEQ ID NO:1, wherein the hybridization conditions include incubation at 42°C in a solution comprising: 50% formamide, 5x SSC (150mM NaCl, 15mM trisodium citrate), 50 mM sodium phosphate (pH7.6), 5x Denhardt's solution, 10% dextran sulfate, and 20 micrograms/ml denatured, sheared salmon sperm DNA, followed by washing in 0.1x SSC at 65°C; and, wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO:1 ; and wherein the first polynucleotide sequence detects *Streptococcus pneumoniae* [and wherein the first polynucleotide sequence is not genomic DNA].

39. (Thrice Amended) An isolated polynucleotide comprising a first polynucleotide sequence, wherein the first polynucleotide sequence encodes a polypeptide comprising SEQ ID NO:2 [and wherein the first polynucleotide sequence is not genomic DNA].

44. (Thrice Amended) An isolated polynucleotide comprising a first polynucleotide sequence, wherein the first polynucleotide sequence encodes a polypeptide consisting of SEQ ID NO:2 [and wherein the first polynucleotide sequence is not genomic DNA].